510(k) Summary of Safety and Effectiveness

This summary of safety and effectiveness information is submitted in accordance with 21 CFR §807.92.

1) Submitter's name, address, telephone number, contact person

Submitted by:
SuperSonic Imagine, S.A.
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K102041

OCT 13 2010

Distributed by:
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Bothell, WA 98011
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Telephone: +1(425) 686 6380

Corresponding Official:

Jacques Souquet
Chief Executive Officer
Telephone: 011 33 442 99 24 35

Date: 2010/07/13

2) Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:

Common/Usual Name: Diagnostic Ultrasound System with Accessories
Proprietary Name: Aixplorer®

Classification:

Regulatory Class: II

Classification Name:	21 CFR Section	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX

3) Substantially Equivalent/Predicate Devices

AIXPLORER® Ultrasound Imaging System (K091970), cleared on 08/12/2009
Siemens Acuson S2000TM Diagnostic Ultrasound System (K072786), cleared on 11/13/2007
Philips iU22 Ultrasound System (K093563), cleared on 02/01/2010

4) Description of Device

The SuperSonic Imagine AIXPLORER® system is a cart based ultrasound imaging system used to perform non-invasive diagnostic general purpose ultrasound imaging studies. The system contains a scan converter and can be coupled to a variety of linear, curved, micro-convex, and motorized linear array transducers to produce images, which are displayed on a LCD monitor. An adjustable control panel with integrated touch screen allows the user to perform an ultrasound exam quickly and efficiently in accordance with ALARA principles. The system also allows the user to perform measurements, capture images to digital memory or to an external device (such as a printer), and review diagnostic studies in the form of a report. The system functions in a manner identical to the predicate devices and transducers for the imaging modes: B-Mode, Color Flow, Pulsed Wave Doppler, Harmonic Imaging, Amplitude Doppler, 3D imaging and for ShearWave™ elastography.

5) Intended Use

The SuperSonic Imagine AIXPLORER® ultrasound system and transducer are intended for general purpose pulse echo ultrasound imaging and Doppler fluid flow analysis of the human body.

6) Indication for Use

The SuperSonic Imagine AIXPLORER® ultrasound system is indicated for use in the following applications: Abdominal, Small Organs, Musculoskeletal, Superficial Musculoskeletal, Vascular, Peripheral Vascular, GYN, Pelvic, Pediatric, Urology, Trans-rectal and Trans-vaginal.

The system also provides the ability to measure anatomical structures (Abdominal, Small Organs, Musculoskeletal, Superficial Musculoskeletal, Peripheral Vascular, GYN, Pelvic, Pediatric, Urology, Trans-rectal and Trans-vaginal).

7) Safety Considerations

As a Track 3 ultrasound device, the SuperSonic Imagine AIXPLORER® ultrasound system is designed to comply with the "Standard For Real Time Display Of Thermal And Mechanical Acoustic Output Indices On Diagnostic Ultrasound Equipment" AIUM/NEMA 2004a published by the National Electrical Manufacturers Association as UD -3. With respect to limits on acoustic outputs, the SuperSonic Imagine AIXPLORER® ultrasound system complies with the FDA guideline limits set in the September 9, 2008, 510(k) diagnostic ultrasound guidance.

With regard to general safety, the SuperSonic Imagine AIXPLORER® ultrasound system scanner is designed to comply with IEC 60101 -1 (2005) Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance, and IEC 60601 - 2-37 (2007): Particular Requirements For The Safety Of Ultrasonic Medical Diagnostic And Monitoring Equipment.

The device's acoustic output limits are:

Mechanical Index	1.9 (Maximum)
TIS/TIB	0.1 – 4.0 (Range)
ISPTA (d)	720 mW/cm2
ISPPA (d)	0 – 700 W/cm2

The limits are the same as predicate Track 3 devices. These considerations apply to all modes the system offers.

8) Comparison to Predicate Devices

The SuperSonic Imagine AIXPLORER® system and transducers are substantially equivalent to the predicate devices with regard to intended use, imaging capabilities, safety and effectiveness.

- The systems are all intended for diagnostic ultrasound imaging and fluid flow analysis.
- The systems have the same clinical indications for use.

- The systems have the same B-Mode (grayscale imaging) and Doppler capabilities.
- The systems have similar capability in terms of harmonic imaging, spatial compound imaging, elastography imaging and other image post-processing features to improve the image quality and aid in clinical evaluation and diagnosis.
- The transducers are similar in materials, manufacture and clinical capability.
- The systems are manufactured with materials which have been evaluated and found to be safe for the intended use of the device.
- The systems have acoustic power levels which are below the applicable FDA limits.
- The systems have similar capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.
- The systems have been found to be manufactured in compliance with approved electrical and physical safety standards.

9) Conclusion

The documentation provided demonstrates that:

1) The system and transducers are substantially equivalent to the predicate devices.
2) There are no new questions of safety and effectiveness concerning the SuperSonic Imagine AIXPLORER® ultrasound system and transducers.
3) The ultrasound device has been scientifically evaluated and has been demonstrated to be at least as safe and effective as the predicate devices cited in item 3.
   The system's acoustic power levels are below the applicable FDA limits.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. Jacques Souquet
CEO
SuperSonis Imaging
Les Jardins de la Duranne-bât. E & F, 510 rue René Descartes
Aix-en-Provence, 13857
FRANCE

Re: K102041
Trade/Device Name: AIXPLORER® Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, ITX, and IYN
Dated: July 13, 2010
Received: July 19, 2010

Dear Mr. Souquet:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the AIXPLORER® Ultrasound System, as described in your premarket notification:

Transducer Model Number

SL15-4 Transducer (1D Linear Array)
SC6-1 Transducer (Curved Array)
SE12-3 Transducer (Endocavity)
SLV16-5 Tranducer (Motorized Linear)

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

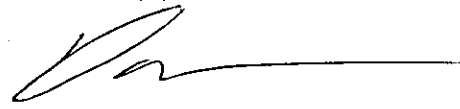
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Paul Hardy at (301) 796-6542.

Sincerely yours,



David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

Diagnostic Ultrasound Indications for Use

510(k) number (if known):
Device Name: AIXPLORER® Ultrasound System
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Indications for Use:
The SuperSonic Imagine AIXPLORER® ultrasound system is indicated for use in the following applications: Abdominal, Small Organs, Musculoskeletal, Superficial Musculoskeletal, Vascular, Peripheral Vascular, GYN, Pelvic, Pediatric, Urology, Trans-rectal and Trans-vaginal.

The system also provides the ability to measure anatomical structures (Abdominal, Small Organs, Musculoskeletal, Superficial Musculoskeletal, Peripheral Vascular, GYN, Pelvic, Pediatric, Urology, Trans-rectal and Trans-vaginal).

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(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K102041

Diagnostic Ultrasound Indications for Use

510(k) Number (if known):
Device Name: SL15-4 transducer (1D Linear Array Transducer)
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P		P		P	P 1, 2, 3	P 4, 5, 6, 7
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N		N		N	N, 1, 2, 3	N 4, 5, 6, 7
	Small Organ (for example Breast, Thyroid, Testicle, Prostate, Penis)	P		P		P	P, 1, 2, 3	P 4, 5, 6, 7
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	P		P		P	P, 1, 2, 3	P 4, 5, 6, 7
	Musculo-skeletal (Superficial)	P		P		P	P, 1, 2, 3	P 4, 5, 6, 7
	Intravascular							
	GYN							
	Pelvic							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel	P		P		P	P, 1, 2, 3	P 4, 5, 6, 7
Vessel	Other (Specify)							

N = new indication; P = previously cleared by FDA (K091970)

Additional Comments:

1: Combined modes include: B+ Color Flow
2: Combined modes include: B+ ShearWave™ Elastography
3: Combined modes include: B+ Pulsed Wave
4: Harmonic Imaging
5: Spatial Compounding
6: ShearWave™ Elastography
7: Imaging Guidance for Biopsies

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Diagnostic Ultrasound Indications for Use

510(k) Number (if known):
Device Name: SC6-1 transducer (curved array transducer)
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal (including urology)	N		N		N	N, 1, 2, 3	N, 4, 5, 6, 7, 8
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N		N		N	N, 1, 2, 3	N, 4, 5, 6, 7
	Small Organ (Breast, Thyroid, Testicle, Prostate, penis, etc...)	N		N		N	N, 1, 2, 3	N, 4, 5, 6, 7
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	N		N		N	N, 1, 2, 3	N, 4, 5, 6, 7
	Musculo-skeletal (Superficial)	N		N		N	N, 1, 2, 3	N, 4, 5, 6, 7
	Intravascular							
	GYN	N		N		N	N, 1, 2, 3	N, 4, 5, 6, 7
	Pelvic	N		N		N	N, 1, 2, 3	N, 4, 5, 6, 7
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N		N		N	N, 1, 2, 3	N, 4, 5, 6, 7
	Other (Specify)	N		N		N	N, 1, 2, 3	N, 4, 5, 6, 7

N = new indication; P = previously cleared by FDA (K091970)

Additional Comments:
1: Combined modes include: B+ Color Flow
2: Combined modes include: B+ ShearWave™ Elastography
3: Combined modes include: B+ Pulsed Wave
4: Harmonic Imaging
5: Spatial Compounding
6: ShearWave™ Elastography
7: Imaging Guidance for Biopsies
8: Contrast mode

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Diagnostic Ultrasound Indications for Use

510(k) Number (if known):
Device Name: SE12-3 transducer (endocavitary transducer)
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (for example Breast, Thyroid, Testicle, Prostate, penis, etc...)	N		N		N	N, 1, 2, 3	N, 4, 5, 6, 7
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	N		N		N	N, 1, 2, 3	N, 4, 5, 6, 7
	Trans-vaginal	N		N		N	N, 1, 2, 3	N, 4, 5, 6, 7
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	GYN	N		N		N	N, 1, 2, 3	N, 4, 5, 6, 7
	Pelvic	N		N		N	N, 1, 2, 3	N, 4, 5, 6, 7
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)	N		N		N	N, 1, 2, 3	N, 4, 5, 6, 7

N = new indication; P = previously cleared by FDA (K091970)

Additional Comments:
1: Combined modes include: B+ Color Flow
2: Combined modes include: B+ ShearWave™ Elastography
3: Combined modes include: B+ Pulsed Wave
4: Harmonic Imaging
5: Spatial Compounding
6: ShearWave™ Elastography
7: Imaging Guidance for Biopsies

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510K K162041

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Diagnostic Ultrasound Indications for Use

510(k) Number (if known):
Device Name: SLV16-5 transducer (motorized linear transducer)
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	N		N		N	N, 1, 2, 3	N 4, 5, 6, 7, 9
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N		N		N	N, 1, 2, 3	N 4, 5, 6, 7, 9
	Small Organ (for example Breast, Thyroid, Testicle, Prostate, penis, etc...)	N		N		N	N, 1, 2, 3	N 4, 5, 6, 7, 9
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	N		N		N	N, 1, 2, 3	N 4, 5, 6, 7, 9
	Musculo-skeletal (Superficial)	N		N		N	N, 1, 2, 3	N 4, 5, 6, 7, 9
	Intravascular							
	GYN							
	Pelvic							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel	N		N		N	N, 1, 2, 3	N 4, 5, 6, 7, 9
Vessel	Other (Specify)							

N = new indication; P = previously cleared by FDA (K091970)

Additional Comments:
1: Combined modes include: B+ Color Flow
2: Combined modes include: B+ ShearWave™ Elastography
3: Combined modes include: B+ Pulsed Wave
4: Harmonic Imaging
5: Spatial Compounding
6: ShearWave™ Elastography
7: Imaging Guidance for Biopsies
9: 3D Imaging

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